AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY JUNE 21, 2007

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 501

Introduced by Assembly Members Swanson and Hancock (Coauthor: Assembly Member Dymally)

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act also prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would, ~~if any specified conditions are met,~~ require a pharmaceutical manufacturer whose product is administered for home

use through a prefilled syringe, prefilled pen, or other prefilled injection device to *arrange to* provide, ~~at no additional charge~~ *upon request from a consumer,* a postage prepaid, mail-back sharps container~~, for the safe disposal of the used device~~ *that has been approved by the United States Postal Services and the department*.

~~The bill would, if these specified conditions are not met, require the pharmaceutical manufacturer to either provide the mail-back container or provide a toll-free telephone number for persons to receive information about safe needle disposal methods in their community.~~

~~The bill would require the pharmaceutical manufacturer to keep specified records and make them available to the State Department of Public Health and the California Integrated Waste Management Board.~~

The bill would also authorize pharmaceutical manufacturers to provide to their consumers concise information on specified disposal options.

Vote: majority. Appropriation: no. Fiscal committee: ~~yes~~ *no*. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 1 million Californians must self-inject prescription medications annually to treat a broad range of serious health problems.

(b) The use of prefilled syringes, prefilled pens, and other prefilled devices with needles is an effective method of prescription drug delivery and is expected to increase significantly in the future. Prefilled syringes, prefilled pens, and other prefilled devices with needles are clearly identified and linked to specific pharmaceutical manufacturers for the provision of their product to California residents.

(c) The increased use of prefilled syringes, prefilled pens, and other prefilled devices with needles will generate millions of home-generated sharps each year. Prefilled pen devices are being used for the treatment of some of the most serious health conditions such as HIV/AIDS, hepatitis C, and many other diseases. If improperly disposed in solid waste and recycling containers these needles will result in significant public health risks.

(d) The Legislature has found that sharps mail-back programs utilizing containers and packaging approved by the United States Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that the cooperative efforts of the pharmaceutical industry are needed to develop a safe needle disposal system for California.

SEC. 2. Section 118288 is added to the Health and Safety Code, to read:

~~118288. (a) Effective January 1, 2009, a pharmaceutical manufacturer whose product is administered for home use via a prefilled syringe, prefilled pen, or other prefilled injection device shall, with respect to each person to whom the product is dispensed, comply with subdivision (b) no later than 30 days after the product has been dispensed.~~

~~(b) In accordance with subdivision (a), a pharmaceutical manufacturer shall meet the following requirements:~~

~~(1) A pharmaceutical manufacturer shall provide, at no additional charge, a postage prepaid, mail-back sharps container, to be mailed to an approved medical waste treatment facility for treatment and disposal if any of the following conditions exist:~~

~~(A) The person requests a mail-back sharps container from the pharmaceutical manufacturer.~~

~~(B) A safe needle disposal method, as defined in paragraph (1) of subdivision (g), does not exist in the person's community.~~

~~(C) It would be impractical for the person to use any of the safe needle disposal methods available in his or her community.~~

~~(2) If none of the conditions specified in subparagraphs (A) to (C) of paragraph (1), inclusive, exist, the pharmaceutical manufacturer shall do either of the following:~~

~~(A) Provide, at no additional charge, a postage prepaid, mail-back sharps container, to be mailed to an approved medical waste treatment facility for treatment and disposal.~~

~~(B) Inform the person of a toll-free telephone number, which shall be established by the pharmaceutical manufacturer, for persons to receive information about safe needle disposal methods in their community.~~

~~(c) A mail-back container shall not be used pursuant to this section unless approved by the United States Postal Service and State Department of Public Health.~~

~~(d) When a pharmaceutical manufacturer or local community provides a safe needle disposal method, as defined in paragraph (1) of subdivision (g), the manufacturer or community shall provide evidence of the number of units dispensed and treated. The appropriate pharmaceutical manufacturer shall provide this information to the department or the California Integrated Waste Management Board, at the request of the department or the board, respectively, in order to document that prefilled devices to which this section applies are being disposed of properly and diverted from the solid wastestream.~~

~~(e) The pharmaceutical manufacturer shall also make available, at no additional charge, a renewable program that provides postage prepaid mail-back sharps containers to persons already receiving these containers pursuant to subdivision (b).~~

~~(f) This section shall not apply to drugs compounded or dispensed for use within a hospital.~~

~~(g) For purposes of this section, the following definitions shall apply:~~

~~(1) "Safe needle disposal method" includes dropoff collection sites, hazardous waste collection centers, residential special waste pickup services, and mail-back services. "Safe needle disposal method" does not include disposal directly into the solid wastestream or recycling stream, placement into a sharps container, bottle or other container that is then sent to a solid waste landfill without treatment at a medical waste treatment facility.~~

~~(2) "Sharps container" has the same meaning as in Section 117750.~~

118288. (a) Upon request of a consumer of a prefilled syringe, prefilled pen, or other prefilled injection device administered at home, a pharmaceutical manufacturer shall arrange to provide a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(b) A pharmaceutical manufacturer may provide to its consumers concise information on convenient locally available safe needle disposal options.

(c) For purposes of this section, "sharps container" has the same meaning as in Section 117750.

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